Doc Code: AP.PRE.REQ

PTO/SB/33 (07-05)
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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional): ECV-5783

I hereby certify that this paper and all enclosures are being transmitted electronically to the attention of the Commissioner for Patents
on June 27, 2008
Signature /Guy Cumberbatch, Reg. No. 36,114/
Typed or printed name Guy Cumberbatch

Application Number	Filed
10/811,565	March 29, 2004

First Named Inventor: Marquez et al.

Art Unit	Examiner
3738	Christopher D. Prone

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

- ☐ applicant/inventor.
- ☐ assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)
- ☑ attorney or agent of record. Registration number 36,114
- ☐ attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____

/Guy Cumberbatch, Reg. No. 36,114/
Signature

Guy Cumberbatch
Typed or printed name

(805) 201-3006
Telephone number

June 27, 2008
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☐ *Total of _____ forms are submitted.

Docket No. ECV-5783

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Marquez, et al.	Group Art Unit: 3738
Application No.: 10/811,565	Examiner: Christopher D. Prone
Filing Date: March 29, 2004	**Customer Number: 30452**
For: CONTROLLED SEPARATION HEART VALVE FRAME	Confirmation No.: 1380

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Dear Sir:

Responsive to the FINAL Office Action dated October 12, 2007, Applicants request that a pre-appeal conference be convened in the present application.

This request is in 5 pages or less and accompanies submission of PTO/SB/33 and a Notice of Appeal under 37 CFR §41.31.

A Petition under 37 CFR §1.137 to Revive the present application accompanies this filing.

REMARKS

Claims 1-18 remain pending.

Per the pilot program for these pre-appeal conferences, no amendments are submitted with the filing of this request.

Claims 1-18 stand rejected under 35 U.S.C. §103(a), as being obvious over U.S. Patent No. 6,736,845 to Marquez, et al. in combination with U.S. Patent No. 6,696,169 (equivalent of WO 00/53356 to Klöckner, et al.). Applicants respectfully disagree with the rejection and request reconsideration.

As explained previously, Marquez, et al. disclose a stent assembly described, in pertinent part, as seen at col. 10, lines 6-43,:

> The final component of the stent assembly 46 is an attachment means 90 for joining each of a cloth-covered stent members 74. Preferably, the attachment means 90 comprises threads or sutures sewn through the central holes in each of the circular tips 80, as shown in FIG. 5, although other suitable attachment means could be used, such as rings, cinches, or the like. The attachment means 90 may be wrapped around or sewn through the cloth cover 72. In joining the tips 80, the attachment means 90 are desirably not wrapped extremely tightly, but are instead provided with some slack to permit relative movement of the tips, as will be described below. When the stent members 74 are attached, as seen in FIG. 5, the stent 70 exhibits three cusps corresponding to the cusp region 76 of each member, and three upstanding commissures defined by the juxtaposition of adjacent pairs of commissure regions 78.
>
> ...
>
> In a preferred embodiment of the present invention the attachment means 90 comprises a non-bioresorbable material to ensure that the individual stent members 74 are maintained in the shape of the stent 70. In an alternative configuration, however, the attachment means 90 comprises a bioresorbable material that dissolves over a period of time after implantation.... As a consequence, each individual stent member 74 and associated leaflet 72 moves entirely independently of the others, albeit all oscillating with the natural contractions and expansions of the surrounding aortic wall. Such independent leaflet movement may greatly reduce any potential pressure drop across the valve.

Marquez, et al. does not disclose the presently claimed support frame (stent) having a substantially continuous stiffness along the cusps and commissures and designed to fracture upon repeated relative movement of the cusps after implantation.

Marquez, et al. instead discloses flexible commissures that permit the separate cusps to pivot with respect to one another. In one embodiment, the commissures may be bioresorbable so as to dissolve over a period of time after implantation and permit each individual stent member 74 and associated leaflet 72 to move entirely independently of the others. The specific embodiment cited by the Examiner shows sutures 90 which connect the separate stent members 74 and may or may not be bioresorbable. Note the passage above which states that "In joining the tips 80, the attachment means 90 are desirably not wrapped extremely tightly, but are instead provided with some slack to permit relative movement of the tips, ..." That is, the sutures permit significant relative cusp movement even prior to implant and dissolution.

Claim 1 specifies a support frame that exhibits a substantially continuous stiffness along the cusps and commissures similar to that resulting from the cusps and commissures being formed integrally. The support member commissures are designed to fracture upon repeated relative movement of the cusps after implantation.

Examiner Prone mis-characterizes Marquez, et al. as having "a plurality of ear shaped commissures 60 further comprising a fragile bridge 90..." The "bridge" is not fragile, instead the "bridge" is highly flexible. The various "attachment means 90" of Marquez, et al. include sutures, rings, etc. that *hold circular tips 80 together* with some slack to permit relative movement. In one version, the attachment means 90 are bioresorbable, which is the only variant that separates after implant. Even the bioresorbable embodiment starts off as being highly flexible. The intent in all of the embodiments is to provide flexibility between the cusps *without fracture*, and in one case to enable gradual resorption. Designing the commissures to fracture would be counter to the intent of the invention of Marquez, et al. Moreover, none of the attachment means 90 of Marquez, et al. renders the support frame substantially continuously stiff along its cusps and commissures similar to that resulting from the cusps and commissures being formed integrally. If that were the case, the goal of great flexibility between the cusps would be thwarted.

Examiner Prone states that Marquez, et al. does not disclose a support frame of a continuous homogeneous material. However, note the embodiment of Fig. 22 which is a one

piece stent having coil spring tips 334. This configuration further illustrates the difference between the present invention and the various embodiments of Marquez, et al. The former involves commissures having a point of weakness designed to fracture upon repeated relative movement of the cusps after implantation, while the latter exhibits highly flexible commissures that are not designed to fracture but instead to provide pivot points for the stent cusps.

The Examiner relies on Klöckner, et al. to contribute to Marquez, et al. "a continuous homogeneous metal sheet [made] with dedicated thinner weak portions as break points in the same field of endeavor for the purpose of ease of production." Thus, the Examiner deduces, it would have been obvious "to combine the teaching of continuous homogeneous breakable connections as taught by [Klöckner] with the implant of Marquez in order to simplify production and reduce costs."

Applicants note that the publication to Klöckner, et al. pertains to an expanded metal mesh cut so that certain links remain joined at nodes configured as break points. The resulting expanded metal mesh can be handled and worked just as easily as normal expanded metal mesh. And, at the paragraph bridging cols. 1 and 2:

> The mesh can be filled out or coated with curing or elastomeric polymerizing or dry substances or compounds and thus are useful e.g. as lathing as well as in roofing applications as products having become popular as "lead replacements". Further possible applications include: 1. spacers for cavity claddings, 2. tailored packings for spherical objects and the like, 3. drying grids and filter cages for industrial and domestic purposes, 4. mattings as employed in automotive repair as a replacement for glass-fiber plastics.

First, Applicants contest the statement by the Examiner that this is "in the same field of endeavor" as heart valve fabrication. Applicants fail to see how a metal mesh product for industrial uses informs one of skill in the art of designing heart valves. There is no motivation given by the Examiner for borrowing the disclosure of Klöckner, et al. other than generalized and entirely abstract benefit of simplifying production and reducing costs. How is production of single heart valve support frames simplified, and how are costs reduced, by incorporating a manufacturing process for a large sheet metal mesh with numerous nodular break points? As

described in col. 3 at the beginning of the Detailed Description of Klöckner, et al., the metal mesh is "conventionally produced" using top and bottom blades. This process is far removed from the much more careful and exacting formation of heart valve stents.

Perhaps more importantly, Examiner Prone fails to explain why one of skill in the art (without hindsight) would wish to provide commissures that fracture upon repeated relative movement of the cusps after implantation. To borrow from Klöckner, et al., or any other disclosure of frangible metal connections, requires some motivation. Applicants assert that there has been no prime *facie case* made out sufficient to suggest to one of skill in the art to combine the references.

Accordingly, Claims 1-18 are allowable over the combination of Marquez, et al. and Klöckner, et al.

Examiner Prone also cites several other old patents that teach breakable metal joints. USPN 658,598 pertains to a spectacle manufacturing technique, USPN 2,247,499 pertains to a screw manufacturing technique, and USPN pertains to a pool ball manufacturing technique. The existence of frangible connections in various unrelated fields provides one of skill in the art with no greater insight prior to the present invention for forming the claimed heart valve support stent. Applicants respectfully find these references, as with Klöckner, et al., to be irrelevant.

Based on the above amendments and remarks, Applicants believe that claims 1-18 are in condition for allowance. If there is any further hindrance to allowance, the Examiner is encouraged contact the undersigned by telephone.

Respectfully submitted,

/Guy Cumberbatch, Reg. No. 36,114/

Date: June 27, 2008

Guy Cumberbatch, Reg. No. 36,114
(805) 201-3006
c/o Rajiv Yadav, Ph.D., Esq., Reg. No. 43,999
Edwards Lifesciences
Law Department
One Edwards Way
Irvine, California 92614

Telephone: (949) 250-6801
Facsimile: (949) 250-6850
Customer No. 30452